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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/507,348

09/13/2004

Gioacchino Coppi

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3855

466 7590 04/13/2007
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EXAMINER

NGUYEN, TUAN VAN

ART UNIT

PAPER NUMBER

3731

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
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3 MONTHS

04/13/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No. 10/507,348	Applicant(s) COPPI, GIOACCHINO	
	Examiner Tuan V. Nguyen	Art Unit 3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 August 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4,6-8 and 10-18 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4,6-8 and 10-18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 13 September 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Amendment After Non-Final Rejection

1. According to the Amendment After Non-Final Rejection applicants filed on January 17, 2007, applicant cancels claims 5 and 9 and adds claims 15-18. Now, claims 1-4, 6-8 and 10-18 are pending in this present application.

Response to Amendment

2. Applicant's arguments filed on January 17, 2007, with respect to claims 1-8 and 10-14 have been fully considered but they are moot in view of new ground of rejection.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. Claim 13 is rejected under 35 U.S.C. 102(e) as being anticipated by
Duhaylongsod et al. (U.S. 6,241,741).

5. Referring to claim 13, Duhaylongsod discloses (see Figs. 1, 1A, 3, and 3A) an anastomosis device comprising: a tubular connecting element 26 having a first end 34' and a second end (opposite of 34') and first end bears a plurality of barbs 36 or outwardly-projecting slender elements arranged in proximity of at least one of the first end; a tubular prosthesis 12 comprising biocompatible material, wherein the tubular prosthesis is inserted into the tubular connecting element 26 and folded around at 34' so that the outwardly projecting slenders or barbs 36 puncture the tubular prosthesis 12 at everted end 16 (see col. 3, lines 36-60; col. 4, lines 26-46; and col. 6, lines 60-68).
6. **Claim 13 is rejected under 35 U.S.C. 102(e) as being anticipated by Sakura, jr. (U.S. 4,214,587).**
7. Referring to claim 13, Sakura discloses (see Figs. 1-2 and 9) an anastomosis device comprises an annular element or tubular element having a first portion (opposite of reference number 11) or first end and a second portion (11) or second end and bears a plurality of outwardly-projecting slender elements (12) arranged in proximity of the first end; a tubular prosthesis (30), wherein the prosthesis is inserted into the tubular element and folded around at least an end of the tubular element with outwardly projecting slender elements so that the outwardly projecting slender elements puncture the prosthesis (see col. 3, line 50 to col. 4, line 20 and col. 5, lines 13-20).

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

10. **Claims 11, 13 and 17-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Duhaylongsod et al. (U.S. 6,241,741) in view of Noble (U.S. 3,221,746).**

11. Referring to **claims 11 and 13**, Duhaylongsod discloses (see Figs. 1, 1A, 3, and 3A) an anastomosis device comprising: a tubular connecting element 26 having a first end 34' and a second end (opposite of 34') and first end bears a plurality of barbs 36 or outwardly-projecting slender elements arranged in proximity of at least one of the first end; a tubular prosthesis 12 comprising biocompatible material, wherein the tubular prosthesis is inserted into the tubular connecting element 26

and folded around at 34' so that the outwardly projecting slenders or barbs 36 puncture the tubular prosthesis 12 at everted end 16 (see col. 3, lines 36-60; col. 4, lines 26-46; and col. 6, lines 60-68). Duhaylongsod discloses the invention substantially as claimed except for the second end also has barb.

12. Still referring to **claims 11 and 13**, Noble discloses (see Figs. 1-3) a device for anastomosis, wherein the device comprises a tubular connecting element having a first end and a second end and both ends bear a plurality of outwardly-projecting barb 12, 13, the free end of barbs facing towards an opposite end from an end at which the barbs are arranged. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made by the applicant to use add second end having barbs to tubular element 26, as disclosed by Noble, to incorporate into the device, as disclosed by Duhaylongsod, because this will provide the surgeon the option of securely connecting the second end of the tubular connecting element to a severed blood vessel as quick as the first end as suggested by Noble (see col. 1, line 45 to col. 2, lines 73).

13.

14. **Claims 1, 2, 11, and 15-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Duhaylongsod et al. (U.S. 6,241,741) in view of Goicoechea (U.S. 6,010,530).**
15. Referring to **claims 1, 2, 11, 15 and 16**, Duhaylongsod discloses (see Figs. 1, 1A, 3, and 3A) an anastomosis device comprising: a tubular connecting element 26 having a first proximal end 34' and a second distal end (opposite of 34') and first

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end bears a plurality of barbs 36 or outwardly-projecting slender elements arranged in proximity of at least one of the first end wherein the barbs are puncturing through the thickness of the prosthesis, Figure 1A shown the barbs 36 appear to be projected toward to the second distal end for the purpose of securing the everted portion of prosthesis over the tubular connecting element (added weight to examiner observation, Kleshinski of Patent No. 5,755,778, Sakura of Patent No. 4,214,587, and Noble of Patent No. 3,221,746, they all disclosed the barbs are projected toward to the free end of the everted portion of the prosthesis); a tubular prosthesis 12 comprising biocompatible material, wherein the tubular prosthesis is inserted into the tubular connecting element 26 and folded around at 34' so that the outwardly projecting slenders or barbs 36 puncture the tubular prosthesis 12 at everted end 16 (see col. 3, lines 36-60; col. 4, lines 26-46; and col. 6, lines 60-68). Referring to **claims 17 and 18**, with respect to the limitation "the prosthetic element is circumferentially inelastic". Duhaylongsod discloses the graft 12 is a synthetic graft material such as Dacron or Goretex graft (see col. 6, lines 61-63). Duhaylongsod discloses the invention substantially as claimed except for the truncoconical profile with a decreasing transversal section in a direction going from the first proximal end to the second distal.

16. Still referring to **claims 1, 2, 11, and 15-18**, Goicoechea discloses (see Fig. 4B) an endovascular prosthesis 10 is designed to fit within a tapered section of an artery wherein the tapering prosthesis having a truncoconical profile with a decreasing transversal section in a direction going from the first proximal end (left side of Fig.

4B) to the second distal (right side of Fig. 4B) (see col. 5, line 58 to col. 6, lines 25). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made by the applicant to use the tapering design, as disclosed by Goicoechea, to incorporate into the device, as disclosed by Duhaylongsod, to gain the advantage of having a connector that fit or conform within a tapered section of an artery as suggested by Goicoechea.

17.

18. **Claims 3, 4, 6, 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Duhaylongsod et al. (U.S. 6,241,741) in view of Goicoechea (U.S. 6,010,530) further in view of Noble (U.S. 3,221,746).**

19. Referring to **claims 3, 4, 6 and 14**, the modified device of Duhaylongsod discloses the invention substantially as claimed except for the second end also has barb. However, Noble discloses (see Figs. 1-3) a device for anastomosis, wherein the device comprises a tubular connecting element having a first end and a second end and both ends bear a plurality of outwardly-projecting barb 12, 13, the free end of barbs facing towards an opposite end from an end at which the barbs are arranged. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made by the applicant to use add second end having barbs to tubular element 26, as disclosed by Noble, to incorporate into the device, as disclosed by Duhaylongsod, because this will provide the surgeon the option of securely connecting the second end of the tubular connecting element to a severed blood vessel as quick as the first end as suggested by Noble (see col. 1,

line 45 to col. 2, lines 73). Furthermore, it would have been obvious matter of design choice to one of ordinary skill in the art to includes barbs to tubular element 26, as disclosed by Noble, to incorporate into the second end of the device of Duhaylonsod, because Applicant has not disclosed that the barbs on the second end of the tubular element provides an advantage, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected the modified device of Duhaylonsod, and applicant's invention, to perform equally well.

20. **Claims 7 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Duhaylonsod et al. (U.S. 6,241,741) in view of Goicoechea (U.S. 6,010,530) further in view of Noble (U.S. 3,221,746) and further in view of Grudem (U.S. 6,511,491).**
21. Referring to **claims 7 and 8**, the modified device of Duhaylonsod discloses the invention substantially as claimed except for the slender elements located on the first proximal end are reciprocally distanced at a smaller step and greater density of slender elements with respect to a step at which the slender elements arranged on the second distal end and the slender elements of the first proximal end are longer than the slender elements of the second distal end. However, Grudem disclosed such an arrangement. Grudem disclosed (see Fig. 3) the slender elements are arranged along the circumference of the proximal to the first portion 20 and second portion (40). The slender elements 22, 26 of the first portion (20) or first end are reciprocally distanced at a smaller step with respect to a step at which the slender elements (42) arranged in proximity of the second portion (40) or

second end are reciprocally distanced. The slender elements (22, 26) are longer and more prominent than the slender elements (42). Therefore, it would have been obvious matter of design choice to one of ordinary skill in the art at the time the invention was made by the applicant to incorporate the arrangement of the barbs as suggested by Grudem into the device of Duhaylongsod because Applicant has not disclosed that such arrangement of the barbs on the ends of the tubular element provides an advantage, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected the modified device of Duhaylongsod, and applicant's invention, to perform equally well.

22. **Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Duhaylongsod et al. in view of Goicoechea further in view of Hughes et al. (U.S. 4,728,328).**
23. Referring to claim 10, the modified device of Duhaylongsod discloses the invention substantially as claimed except for the suture is used for tight around the tubular element. Hughes discloses (see Figs. 2 and 5) a prosthesis is connected to an anastomosis element by using thread 30, 40 wound around the prosthesis and the anastomosis to secure the prosthesis to the vessel wherein the barb and the suture as shown in Fig. 5 is not in contact with the blood contacting surface of the vessel thereby discouraging thrombosis (see col. 5, lines 50-63). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made by the applicant to use the thread wound around the prosthesis, the tubular element and vessel, as disclosed by Hughes, to incorporate into the

modified device, as disclosed by Duhaylongsod, because this will improve the security of the connection and avoid thrombosis as suggested by Hughes.

24. **Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Duhaylongsod et al. (U.S. 6,241,741) in view of Noble (U.S. 3,221,746) and further in view of Hughes et al. (U.S. 4,728,328).**
25. Referring to claim 12, the modified device of Duhaylongsod discloses the invention substantially as claimed except for the suture is used for tight around the tubular element. Hughes discloses (see Figs. 2 and 5) a prosthesis is connected to an anastomosis element by using thread 30. 40 wound around the prosthesis and the anastomosis to secure the prosthesis to the vessel and the suture as shown in Fig. 5 is not in contact with the blood contacting surface of the vessel thereby discouraging thrombosis (see col. 5, lines 50-63). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made by the applicant to use the thread wound around the prosthesis, the tubular element and vessel, as disclosed by Hughes, to incorporate into the modified device, as disclosed by Duhaylongsod, because this will improve the security of the connection and avoid thrombosis as suggested by Hughes.
26. **Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over Duhaylongsod et al. in view of Noble further in view of Goicoechea and further in view of Hughes et al. (U.S. 4,728,328).**
27. Referring to claim 16, the modified device of Duhaylongsod discloses the invention substantially as claimed except for the suture is used for tight around the tubular

element. Hughes discloses (see Figs. 2 and 5) a prosthesis is connected to an anastomosis element by using thread 30. 40 wound around the prosthesis and the anastomosis to secure the prosthesis to the vessel and the suture as shown in Fig. 5 is not in contact with the blood contacting surface of the vessel thereby discouraging thrombosis (see col. 5, lines 50-63). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made by the applicant to use the thread wound around the prosthesis, the tubular element and vessel, as disclosed by Hughes, to incorporate into the modified device, as disclosed by Duhaylongsod, because this will improve the security of the connection and avoid thrombosis as suggested by Hughes.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tuan V. Nguyen whose telephone number is 571-272-5962. The examiner can normally be reached on M-F: 9:00 AM - 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anh Tuan Nguyen can be reached on 571-272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Tuan V. Nguyen
April 3, 2007


ANH TUAN T. NGUYEN
SUPERVISORY PATENT EXAMINER
